



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,945	08/13/2003	Barry N. Gellman	01194-448001 / 02-229	6981

26161 7590 06/16/2005

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/639,945

Applicant(s)

GELLMAN ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 16-27 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 3-15 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03142005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed March 14, 2005. The Examiner acknowledges the amendments to the specification; the amendments to the drawings; the amendments to claims 1, 3, 6, 8, 13-17, 29 and 32; and the cancellation of claims 33 and 34. Claims 1-32 are pending.

Drawings

2. The drawings were received on March 14, 2005. These drawings are acceptable.

Specification

3. The amendments to the specification were received on March 14, 2005. These amendments are acceptable.

4. The disclosure is objected to because of the following informalities: at page 10, line 9, --tube-- should be inserted following "control" (second occurrence). Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 16-24 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al. ('212). Jones et al. teach an intracorporeal marker delivery device (10) and needle biopsy system. The device and system includes a portion locatable inside the body capable of sampling formed by a stylet (18) having a sampling region (17), a marker lumen (12) extending through the stylet from the proximal end of the stylet to a marker exit opening, and a cannula (42). The stylet (18) and cannula (42) are relatively moveable along the stylet axis to position the cannula over the sampling region. A supply of sample markers (15) are sequentially disposed in the lumen (see Figure 1A), generally parallel to the stylet, and are releasable from the sampling portion. A marker is capable of being located between the stylet and cannula, at least in the case of premature deployment. A control handle portion (20) at least temporarily houses the markers and a marker pusher is used to selectively locate markers in the sampling portion. The pusher (21) is actuated in the region of the handle portion. The markers may be elongated elements that are capable of indicating the axial length of the tissue region where the sample has been taken. The markers are biodegradable and include regions along its length distinguishable by MRI, ultrasound or fluoroscopy. In operation, the stylet of device is inserted into a tissue

Art Unit: 3736

mass, relative motion between the stylet and the cannula is caused to locate the cannula over the sampling region at least while the stylet is inserted into the tissue mass, and while the stylet is removed from the tissue a marker is delivered from the sampling portion into the tissue. The stylet is then inserted into the tissue mass a second time and a second marker may be delivered into the tissue mass.

7. Claims 1, 17, 19-23, 25 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Foerster et al. ('055). Foerster et al. teach a needle system for delivering markers to a biopsy site. The system includes a portion locatable inside the body capable of sampling formed by a stylet having a sampling region and a cannula (see the apparatus of U.S. RE 34,056 as cited at col. 9, lines 5-20). A marker lumen (54) is arranged to extend through the stylet from the proximal end of the stylet to a marker exit opening. The stylet and cannula are relatively moveable along the stylet axis to position the cannula over the sampling region. A supply of sample markers (12) are sequentially disposed in the lumen (see column 10, lines 7-9), generally parallel to the stylet, and are releasable from the sampling portion. A pusher is actuated to deploy the markers. The markers are biodegradable and include regions along its length distinguishable by MRI, ultrasound or fluoroscopy. In operation, the stylet of device is inserted into a tissue mass, relative motion between the stylet and the cannula is caused to locate the cannula over the sampling region at least while the stylet is inserted into the tissue mass, and while the stylet is removed from the tissue a marker is delivered from the sampling portion into the tissue. The stylet is then inserted into the tissue mass a second time and a second marker may be delivered into the tissue mass.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. ('055) in view of Sinanan et al. ('715). Foerster et al., as discussed hereinabove, teach all of the limitations of the claims except that the marker is magnetically fixed to the exterior of the stylet. Sinanan et al. teach an anatomical marker that is magnetically attached to an introducer stylet in order to prevent premature deployment or shifting of the marker until the marker is securely affixed to a desired tissue area within the body. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to magnetically fix the marker to the stylet of Foerster et al. in light of the teachings of Sinanan et al. so that the marker may not shift or be prematurely deployed from the stylet as the marker is axially translated upon advancement of the stylet and cannula and released into tissue upon retraction of the cannula to expose the stylet and marker.

Allowable Subject Matter

10. Claims 3-5, 8-15 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 3-15, no prior art of record teach or fairly suggest a needle biopsy system, as claimed by Applicant, where the marker lumen extending from a proximal end of the stylet to a marker exit opening is positioned between the stylet and the cannula.

Regarding claim 28, no prior art of record teach or fairly suggest a needle biopsy system, as claimed by Applicant, where a marker is magnetically fixed to the exterior of the stylet and the marker is translated by axial motion of the cannula to a location where it is magnetically repulsed from the cannula.

Response to Arguments

12. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Burney ('700), Dowlatshahi ('366), Sirimanne ('437) and Sinanan ('715), alone or in combination, do not teach or suggest a needle biopsy system including a marker lumen extending from a proximal end of the stylet to a marker exit opening. This argument is moot in view of the new grounds of rejection citing one of Jones et al. ('212) and Foerster et al. ('055) set forth hereinabove.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
June 10, 2005